PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 13 OCT 2004
WIPO PCT

Applicant's or agent's file reference 13340-6	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CA 03/01613	International filing date *(day/month/year)* 24.10.2003	Priority date *(day/month/year)* 24.10.2002
International Patent Classification (IPC) or both national classification and IPC G01N33/543		
Applicant SPECTRAL DIAGNOSTICS INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 63 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19.05.2004	12.10.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Diez Schlereth, D Telephone No. +49 89 2399-7488

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA 03/01613

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-34	received on 19.05.2004 with letter of 31.03.2004

Claims, Numbers

1-40	received on 19.05.2004 with letter of 31.03.2004

Drawings, Sheets

1, 3, 10, 11, 15, 16, 18, 20-22	as originally filed
2, 4-9, 12-14, 17, 19	received on 19.05.2004 with letter of 31.03.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	8-19,28-29,33-34,38-39
	No:	Claims	1-7,20-27,30-32,35-37,40
Inventive step (IS)	Yes:	Claims	15-19
	No:	Claims	1-14,20-40
Industrial applicability (IA)	Yes:	Claims	1-40
	No:	Claims	

2. Citations and explanations

   see separate sheet

While the arguments given by the applicant in his letter of 25.09.04 have been considered, this Authority maintains that the present application does not meet the requirements of the PCT for patentability (see items IV and V below), for the following reasons:

- independent claims 1, 6 and 15 define the "sample deposition means" by a desired functional characteristic, which may be achieved by any technical means. Furthermore, it is noted that the wording used to define of said functional characteristic is unclear and open to interpretation, which renders impossible to figure out what is actually the subject-matter for which protection is sought.

- the definition given in independent claims 20 and 30 for the "sample deposition means" is so broad, that it encompasses many deposition means already known from the state of the art.

item IV

The subject-matter of independent claims 1, 6, 20 and 36 is already known from the prior art (see item V below). The requisite for unity of invention (Rule 13.1 PCT) therefore no longer exists inasmuch as a technical relationship involving one or more of the same or corresponding special technical features in the sense of Rule 13.2 PCT does not exist between the subject-matter of the following groups of claims:

"Lateral flow immunodiagnostic devices having a carrier and sample deposition means associated with said carrier, *wherein the sample deposition means"*

(i) are adapted to deposit a sample onto it as a sample band that is linear and transverse to the desired flow direction (claims 1-5); or

(ii) are adapted to deposit a sample onto the carrier as a sample band that is linear and has a width greater than the width of the detection zone (claims 6-19); or

(iii) have a sample delivering channel having two opposed surfaces which are spaced apart such as to promote longitudinal advance of the sample by capillary action (claims 20-35); or

(iv) have a sample injection means having an injection channel in fluid communication with the carrier (claims 36-40).

However, since a complete Search Report has been issued by the International Search Authority, this International Preliminary Examination Report deals with all inventions.

item V

1.) Reference is made to the following documents:

D1: WO-A-00/08466
D2: US-A-5,354,692
D3: WO-A-01/27627
D4: WO-A-01/25789
D5: WO-A-00/77524

2.) The subject-matter of claims 1-7, 20-27, 30-32, 35-37 and 40 is not novel within the sense of Art. 33 (2) PCT, for the following reasons:

D1-D5 disclose several devices for carrying out immunodiagnostic assays in lateral-flow format comprising an absorbent carrier comprising the required immunoreagents disposed thereon and sample deposition means.

In D1 the sample deposition means are formed by pressing the absorbent carrier against the inner surface of the housing, which has a well and a groove forming a sample delivery channel and a sample circulation channel. This channel system is adapted to move the sample by capillarity and to deposit the sample on the carrier as a sample band which width is larger than that of the detection zone (see figs. 4-5, 9-10). D1 anticipates the subject-matter of claims 1-2, 6, 20, 23-25, 30-32, 35-37 and 40.

In D2 the sample deposition means are formed by engaging the casing having a sample well with a multipad arrangement comprising two stacked pads comprising immunoreagents and acting as sample receiving pads which are connected to an absorbent pad for collecting reacted sample via a bridge wicking pad where the reaction takes place (col. 4, l .15 to col. 5, l. 45; fig. 4). D2 anticipates the subject-matter of claims 1, 3-7, 36 and 40.

In D3 the sample deposition means are formed by a capillary chamber connecting the sample application pad with the detection zone. The depth of the capillary chamber varies gradually being larger on the side of the sample application pad than on the side of the detection zone (figs. 5, 7). D3 anticipates the subject-matter of claims 1, 20-27, 30-32, 35-

37 and 40.

In D4 the sample deposition means are formed by engaging the casing having a sample well with an absorbent strip (fig. 7). D4 anticipates the subject-matter of claims 1-2, 6, 36-37 and 40.

3.) The subject-matter of dependent claims 8-14, 28-29, 33-34 and 38-39 is considered to be novel (Art. 33 (2) PCT), but not inventive within the sense of Art. 33 (3) PCT because it relates to slight constructional changes of the devices of claims 1, 6, 20 or 36, which fall within the routine practice in this technical field and do not seem to result in any unexpected techncial effect.

4.) It would appear that novelty and inventive step (Art. 33 (2) and (3) PCT) could be acknowledged for the subject-matter of claims 15-19, for the following reasons:

The device of claims 15-19 comprises a sample receiving pad in fluid communication with a detection pad, wherein the width of the sample receiving pad is greater than that of the detector pad. This configuration of the pads promotes a convergent flow of sample to the detection zone, which concentrates reagents and analyte while retarding migration of particulates, thereby improving the performance of the device.

The devices of D1 and D4 do not comprise separated pads for receiving sample and for decting analyte. D2-D3 do comprise separated pads for receiving and analyzing the sample but both pads have the same width. D5 is the only document disclosing a test strip having an absorbent pad which is wider than the detection strip. The pad is thought as sample collector reservoir (see figs. 1 and 7).

5.) As a general remark, the attention of the applicant is drawn to the following comment: although claims 1, 6, 15, 20 and 36 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter (an immonodiagnostic device) and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims, therefore, lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of protection. Hence, these claims do not meet the requirements of Art. 6 PCT. In order to overcome this objection, it would appear appropriate to file an ammended set of claims defining the relevant subject-matter in terms of a minimum number of independent claims

in each category followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).